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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/951,733	10/16/97	HARRINGTON	A-433B

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US PATENT OPERATIONS NOA
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EXAMINER

BUGAISKY, G

ART UNIT

1653

PAPER NUMBER

14

DATE MAILED: 07/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/951,733

Applicant(s)
HARRINGTON et al.

Examiner
Gabriele E. Bugaisky

Group Art Unit
1653



☒ Responsive to communication(s) filed on Apr 12, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-33 is/are pending in the application.

Of the above, claim(s) 22-25, 31, and 32 is/are withdrawn from consideration.

☒ Claim(s) 2, 3, 5, 8, 9, 11, 14, 15, 17, and 28-30 is/are allowed.

☒ Claim(s) 1, 4, 6, 7, 10, 12, 13, 16, 18, 19, 26, 27, and 33 is/are rejected.

☒ Claim(s) 20 and 21 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8, p.2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

The amendment of 4/99 is acknowledged. New claim 33 has been added; claims 22-25 and 31-32 remain withdrawn. Claims 1-21, 26-30 and 33 are currently under further consideration.

Information Disclosure Statement

The references on p 2 of paper #8 indeed were considered prior to the last Action. The Examiner thanks Applicants for pointing out that she neglected to initial that page. An initialed copy of that page accompanies this paper.

Claim Objections

Claim 1 is objected to because of the following informalities: in line 2 of part h), the claim recites "55-65 C". Apparently "o" has been omitted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-27 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acids encoding TP2 of SEQ ID NO: 14 and 20, and catalytically active fragments thereof, and the disclosed mutations of the above gene does not reasonably provide enablement for catalytically active variants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. As was stated in the previous Action, the Examiner has noted the definition of "biologically active" which appears on page 15, lines 33-36 and page 16 lines 1-11, which specifies the active fragment must possess telomerase catalytic activity and have one of several recited properties. The statements of the previous rejection are incorporated here. It is noted that Applicants state they have amended these claims to overcome the rejection; however, the claimed variants do not limit the scope to specific SEQ ID NOs; indeed, claim 27 recites no SEQ ID NO.

Claims 4, 6, 10, 12, 16 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding the recited polypeptide, which is free of homologous chromosomal DNA, does not reasonably provide enablement for the chromosomal DNA upon which the DNA encoding the recited polypeptide molecule lies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Applicants have not enabled the DNA of an entire chromosome. It is suggested that Applicants carefully review the specification to avoid new matter before amending

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claim 4; amendment to recite, e.g., "An isolated nucleic acid consisting of" could overcome this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

Claims 1, 7, 13, 19 and 27 remain rejected and claim 33 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Telomerase protein 2 is used by inventors for the purified gene encoding a polypeptide of the telomerase complex. It is noted that the name of a protein does not define it in terms of structure or function. In fact, the name of a protein is arbitrarily assigned by the inventors thereof, and may change over time as more is discovered about the protein. For example, interleukin-1 is also known as lymphocyte activating factor, endogenous pyrogen, leucocyte endogenous mediator, mononuclear cell factor, and catabolin (see Callard et al).

Claims 7, 13 and 19 are included in this rejection as they are dependent claims and do not clarify the ambiguity.

The rejection of claims 1, 7, 13 and 19, and 26-30 under 35 U.S.C. 112, second paragraph, for recitation of % identity and stringent hybridization is withdrawn, based upon the amendments.

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, for recitation of "SEQ ID NO:14 of SEQ ID NO:20" is withdrawn, based upon the amendment.

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The rejection of claim 26 is under 35 U.S.C. 112, second paragraph, for recitation of "proliferation of a cell"

The rejection of claim 28 under 35 U.S.C. 112, second paragraph, for recitation of "decreasing telomerase" is withdrawn, based upon the amendment.

The rejection of claims 29 and 30 under 35 U.S.C. 112, second paragraph, for recitation of an amino acid position without reference to a SEQ ID NO: is withdrawn, based upon the amendment.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 2, 4, 6-8, 10, 12-14, 16 and 18-19 under 35 U.S.C. 102(a) as being anticipated by Nakamura *et al.* is withdrawn, upon review of 08/873039.

Claim Rejections - 35 USC § 103

The rejection of claims 3, 5, 9, 11, 15, 17, 21, 26 and 27 under 35 U.S.C. 103(a) as being unpatentable over Nakamura *et al.* is withdrawn, upon review of 08/873039.

Conclusion

Claims 2, 3, 5, 8-9, 11, 14-15, 17 and 28-30 are allowed.

Claims 20-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 7:30 AM to 4:00 PM on weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bradley L. Sisson, can be reached at (703) 308-3978.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

B. L. Sisson
BRADLEY SISSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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